K121475

**Section 5:** **510(k) Summary**
**TxCell™ Scanning Laser Delivery System**

NOV 2 8 2012

**A. Trade Name**

TxCell™ Scanning Laser Delivery System

**B. Common Name**

Scanning Photocoagulator Slit Lamp Adapter Delivery System

**C. Device Classification**

Laser Instrument, Surgical, Powered (21CFR 878.4810)

**D. Product Code:**

GEX

**E. Establishment Registration Number**

2939653

**F. Manufacturer's Identification**

IRIDEX Corporation
1212 Terra Bella Ave.
Mountain View, CA 94043-1824
(650) -962-8848 Ext. 8872
(650) 940-4710 (FAX)

Official Correspondent

Paul Hardiman
Vice President Regulatory Affairs/Quality Assurance
phardiman@iridex.com

**G. Performance Standards**

Bench testing was performed to compare the laser output variations of single spot and multi-spot scanned applications using the TxCell Scanning Laser Delivery System and a compatible Laser Console. Variations in continuous wave and MicroPulse laser applications were also assessed for both single spot and multi-spot delivery. Results showed that the laser system controls pulse to pulse power variations for both single spot and multi-spot scanning modes to better than 0.5%; and that the duration variability for both single spot and multi-spot scanning modes was less than 0.25%. The test confirmed that the output energy from the TxCell Scanning Laser Delivery System was consistently delivered in both single spot and multi-spot modes while delivering either continuous wave or MicroPulse laser applications. Pulse to pulse variations are controlled by the laser console and are independent of spatial positioning due to changes in spot location by the scanner.

H. **Predicate Devices:**

Family of IRIDEX IQ Laser Systems (IQ 532, IQ 577, IQ 630-670, IQ 810) (K071687)
Quantel SUPRA SCAN™ Delivery System (K100678)
Topcon PASCAL Streamline 577 (K111108)

I. **Product Description:**

The TxCell™ Scanning Laser Delivery System is a slit lamp adapter laser delivery system which is installed by the customer on existing slit lamps in their office or clinic and is used by ophthalmologists to deliver laser energy to various ocular targets. The TxCell™ delivery system delivers laser applications in both single spot mode and multi-spot mode.

The TxCell™ Scanning Laser Delivery System adds the use of multi-spot pattern scanning technology when coupling with commercially available IRIDEX laser systems. This offers existing IRIDEX laser systems the ability to deliver, in addition to standard single spot applications, a full spectrum of multi-spot pattern scanning options through a variety of customer owned slit lamps.

The TxCell™ Scanning Laser Delivery System consists of the following system components:

1. TxCell™ Scanning Slit Lamp Adapter (SSLA) that may be coupled to Zeiss-style or Haag Streit-style slit lamps or the IRIDEX Laser Workstations.
2. TxCell™ Control Box with power supply, scanner controller, drive electronics and electrical connections. The Control Box is paired with an SSLA.
3. Cables to connect the SSLA to the Control Box and the Control Box to the laser console.

The TxCell Scanning Laser Delivery System requires connection to a TxCell compatible Laser Console from the IRIDEX Family of IQ Laser Systems (IQ 532, IQ 577, IQ 810). The touchscreen on the TxCell compatible IQ Family Laser Console accesses a Pattern Selection Screen and the knobs on the Laser Console set the pattern parameters. All other user interface screens and menus are unchanged and operate the same as on the standard IQ Family Laser Console.

## J. Summary of Technological Characteristics

The technological characteristics of the TxCell Scanning Laser Delivery System when coupling with commercially available IRIDEX laser systems (IQ 532, IQ 577 & IQ 810) are substantially equivalent to those of the predicate devices.

| **Manufacturer** | **IRIDEX Corporation** | **IRIDEX Corporation** | **QUANTEL MEDICAL** | **TOPCON Corporation** |
|---|---|---|---|---|
| Device Description | TxCell™ Scanning Laser Delivery System w/ IQ Family Laser (IQ 532, IQ 577, IQ 810) | EasyFit™ Slit Lamp Adapter w/ IQ Family Laser (IQ 532, IQ 577, IQ 810) | SUPRA SCAN™ Delivery System w/ SUPRA 532 | PASCAL® Streamline 577 |
| 510 (k) Number | K121475 | K071687 | K100678 | K111108 |
| Treatment Laser Wavelengths | 532 nm,577 nm, 810 nm | 532 nm,577 nm,810 nm | 532 nm | 577 nm |
| Treatment Laser Sources | Frequency doubled solid-state (532 nm, 577 nm) and direct diode (810 nm) | Frequency doubled solid-state (532 nm, 577 nm) and direct diode (810 nm) | Frequency doubled solid-state | Frequency doubled solid-state |
| Treatment Laser Power | Up to 2 W | Up to 5 W | Up to 2 W | Up to 2 W |
| Duty Cycle | Variable | Variable | Not reported | 100% |
| Repetition Mode | Available with single spot mode only | Available with single spot mode only | Not reported | Available with single spot mode only |
| Aiming Beam λ (power output) | 635 nm; Direct diode (adjustable to < 1mW) | 635 nm; Direct diode (adjustable to < 1mW) | 635 nm | 635 nm; Direct diode (adjustable to < 1mW) |
| Type of Delivery System | Slit lamp adapter with optical fiber connected to a separate laser source | Slit lamp adapter with optical fiber connected to a separate laser source | Slit lamp adapter with optical fiber connected to a separate laser source | Slit lamp adapter with optical fiber with integrated laser source |
| Laser Delivery Modes | Single spot & Multi-spot patterns | Single spot | Single spot & Multi-spot patterns | Single spot & Multi-spot patterns |
| Range of spot sizes for single spot mode | 50 – 500 μm | 50 – 500 μm | 50 – 500 μm | 60 – 400 μm |
| Range of spot sizes for multi-spot mode | 100 – 500 μm | na | 100 – 500 μm | 100 – 400 μm |

## K. Rationale for Substantial Equivalence

The TxCell Scanning Laser Delivery System shares the same or similar indications for use, design features, functional features with, and therefore is substantially equivalent to, the predicate devices.

The TxCell™ Scanning Laser Delivery System is found to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Iridex, Corporation
% Mr. Paul H. Hardiman
Vice President, Regulatory Affairs and Quality Assurance
1212 Terra Bella Avenue
Mountain View, California 94043

November 28, 2012

Re: K121475
Trade/Device Name: TxCell™ Scanning Laser Delivery System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 07, 2012
Received: November 19, 2012

Dear Mr. Hardiman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(K)**
**INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): **K121475**

Device Name: **TxCell™ Scanning Laser Delivery System**

**Indications for Use:**

When the TxCell Scanning Laser Delivery System is connected to the IQ 532 (532 nm), the IQ 577 (577 nm) or the IQ 810 (810 nm) Laser Console, from the IRIDEX Family of IQ Laser Systems and used to deliver laser energy in CW-Pulse, MicroPulse or LongPulse mode, it is intended to be used by a trained ophthalmologist for the treatment of ocular pathology of both the anterior and posterior segments of the eye.

**532 nm**

Indicated for retinal photocoagulation, laser trabeculoplasty, iridotomy, iridoplasty including:

Retinal photocoagulation (RPC) for the treatment of:
- Diabetic retinopathy, including:
  - Nonproliferative retinopathy
  - Macular edema
  - Proliferative retinopathy
- Retinal tears and detachments
- Lattice degeneration
- Age-related macular degeneration (AMD) with choroidal neovascularization (CNV)
- Sub-retinal (choroidal) neovascularization
- Central and branch retinal vein occlusion

Laser trabeculoplasty for the treatment of:
- Primary open angle glaucoma

Laser iridotomy, iridoplasty for the treatment of:
- Angle closure glaucoma

Prescription Use **X** AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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**(Division Sign-Off)** for mxm
**Division of Surgical Devices**
**510(k) Number K121475**

**510(K)**
**INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): **K121475**

Device Name: **TxCell™ Scanning Laser Delivery System**

**577 nm**

Indicated for use in photocoagulation of both anterior and posterior segments including:

Retinal photocoagulation, panretinal photocoagulation of vascular and structure abnormalities of the retina and choroid including:
- Proliferative and nonproliferative diabetic retinopathy
- Choroidal neovascularization
- Branch retinal vein occlusion
- Age-related macular degeneration (AMD) with choroidal neovascularization (CNV)
- Retinal tears and detachments

Laser trabeculoplasty for the treatment of:
- Primary open angle glaucoma

Laser iridotomy, iridoplasty for the treatment of:
- Angle closure glaucoma

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

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**Division of Surgical Devices**
**510(k) Number K121475**

**510(K)**
**INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): **K121475**

Device Name: **TxCell™ Scanning Laser Delivery System**

**810 nm**

Indicated for retinal photocoagulation, laser trabeculoplasty, iridotomy including:

Retinal photocoagulation for the treatment of:
- Diabetic retinopathy, including:
  - Nonproliferative retinopathy
  - Macular edema
  - Proliferative retinopathy
- Retinal tears, detachments and hole
- Lattice degeneration
- Age-related macular degeneration (AMD) with choroidal neovascularization (CNV)
- Sub-retinal (choroidal) neovascularization
- Central and branch retinal vein occlusion

Laser trabeculoplasty for the treatment of:
- Primary open angle glaucoma

Laser iridotomy, iridoplasty for the treatment of:
- Angle closure glaucoma

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Division of Surgical Devices
510(k) Number K121475